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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/025,363	02/18/98	MARK D	P97.1036

HM12/0428

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EXAMINER	
SHARAREH, S	
ART UNIT	**PAPER NUMBER**
1616	4

DATE MAILED: 04/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/025,363	Applicant(s) David Mark et al
	Examiner Shahnam Sharareh	Group Art Unit 1616

☒ Responsive to communication(s) filed on *Feb 18, 1998* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2 & 3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent 5,661,123. The instant claims are drawn to an enteral composition and a method of providing it to the metabolically stressed patients wherein said composition comprising a caloric density of about 1.4 Kcal/ml, a protein

source, a carbohydrate source, a lipid source including a mixture of medium and long chain density triglycerides, a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, a L-Carnitine source, and a beta-carotene source. Although the conflicting claims are not identical and introduce different use and various different concentrations of the ingredients, but they are not patentably distinct from the patented claims, because they fail to add a distinctive limitation to the claims of U.S. Patent 5,661,123.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "100% of U.S. RDA" fails to teach and specify which nutrients meet the U.S. RDA.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-7, 9-13, 15, 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidl et al US Patent 5,504,072.

The instant claims are drawn to an enteral composition comprising a protein source, a carbohydrate source, a lipid source including a mixture of medium and long chain density triglycerides, a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, and a L-

Carnitine source, wherein the composition provides a ratio of non-protein calories per gram nitrogen of at least approximately 90:1. Further the instant claims encompass methods of providing said composition to a patient comprising administration of therapeutically effective amount to the patient wherein said composition is fed through a tube.. Schmidl et al disclose an enteral nutritional formulation that meets the nutritional needs of critically ill and metabolically stressed patients such as patients suffering from trauma, burn, malnutrition, sepsis, cancer, AIDS or other like conditions (see Col 3, lines 34-42). Schmidl et al also disclose an enteral formulation comprising a protein source that can provide approximately 16-25% of the calorie distribution of the composition that can include protein hydrolysate such as whey hydrolysate or alike (see Col 4 lines 51-67), a carbohydrate source, a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, a Vitamin C source (see Col 4 lines 1-51 and Col 8 table), and wherein said formulation provides a non-protein calorie to grams of nitrogen ratio of ranging from 150:1 to 80:1 (see Col 5 lines 64-68 and Col 6 lines 1-11). Schmidl et al further disclose a method for administering said formulation to a patient via various tube-feeding techniques (see Col 7 lines 60-67). Therefore, the nutritional formula of Schmidl et al meets the limitation set forth in the instant claim.

5. Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Cope et al US Patent 5,480,872. The instant claims are drawn to an enteral composition with caloric density of approximately 1.4 Kcal/ml and comprising a protein source comprising approximately 15-21% of the calorie distribution, a carbohydrate source, a lipid source including a mixture of medium and

long chain density triglycerides, a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, a L-Carnitine source, and a beta-carotene source. Further the instant claims encompass methods of providing said composition to a patient comprising administration of therapeutically effective amount to the patient, wherein the protein source consists essentially of partially hydrolyzed whey proteins. Cope et al disclose a high protein, calorically dense (see col 5, lines 8-22) nutritional product for hypermetabolic patients comprising a hydrolyzed protein comprising any suitable source such as whey protein (see Col 9 line 20-46, and 1-12), a source of carbohydrate, a mixture of medium and long chain triglycerides and fatty acids, and other micronutrient such that the said nutritional product meets 100% US RDA's recommendations of all micronutrients contained (see tables 1, 2,5,6). Cope et al also disclose that the said nutritional product can be used both as an oral supplement and for enteral support, administered either orally or by tube feeding (see Col 13, lines 46-51). Since Cope et al disclose an enteral formula comprising a protein source that can contain 19-21% of the calorie distribution of the composition, a lipid source, a protein source, and other micronutrient such that the said nutritional product meets 100% of US RDA's recommendation for contained nutrients, as well as a method for administration; which are within the scope of the instant claims, said claims are anticipated by Cope et al.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

6. Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Gray et al US Patent 5,714,472.

The instant claims are drawn to an enteral composition with caloric density of about 1.4 Kcal/ml comprising a protein source, a carbohydrate source, a lipid source including a mixture of medium and long chain density triglycerides, a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, a L-Carnitine source, and a beta-carotene source. Further the instant claims encompass methods of providing said composition to a patient comprising administration of therapeutically effective amount to the patient. Gray et al teach an enteral nutritional formulation that meets the nutritional needs of critically ill and metabolically stressed patients such as post-surgical patients or patients suffering from trauma, burn or related complications. Said enteral formulation having a caloric density of at least 1.3 Kcal/ml comprising a protein source including protein hydrolysate comprising whey hydrolysate, a carbohydrate source, a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, and a Vitamin C source, wherein said formulation meets the U.S. RDAs recommendations of said nutrients (See col 5 lines 25-38, 65-68, and Col 6 lines 35-42, and Col 7, lines 0-14). Gray et al also disclose a method for providing said formulation to a patient comprising a step of enterally administering to the patient a therapeutically effective amount (see Col 9 and 10, all claims). Therefore, Gray et al's nutritional formula meets the limitation set forth in the instant claim.

6. Claims 1-3, 5, 7-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Cope et al US Patent 5,700,782. The instant claims are drawn to an enteral composition with caloric density of approximately 1.4 Kcal/ml and comprising a protein source comprising approximately 15-21% of the calorie distribution, a carbohydrate source, a lipid source including a mixture of

medium and long chain density triglycerides, a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, a L-Carnitine source, and a beta-carotene source. Further the instant claims encompass methods of providing said composition to a patient comprising administration of therapeutically effective amount to the patient. Cope et al disclose an enteral nutritional product with the caloric density of about 1.2 to 1.5 Kcal/ml comprising a protein source , a carbohydrate source (see col 9, lines 15-55) , a lipid source including a mixture of medium and long chain density triglycerides (see col 3 lines 49-66, and table 4), a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, a L-Carnitine source, a beta-carotene source, and other micronutrient that may be incorporated in the enteral product (see tables 2,3,4,5). Cope et al further disclose the method of providing said enteral or nutritional product to a patient (see col 5, lines 46-56, col 10, lines 13-53). Therefore Cope discloses a nutritional product that meets the limitation set forth in the instant claim.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over TRAUMACAL ™ (Mead Johnson, Document bearing No B00107-180), Trimbo et al US Patent 5,166,189, Stalker et al US Patent 5,661,123, as applied to claim 1-20 above, and in view of Schmidl et al US Patent 5,504,072, Cope et al US Patent 5,480,872, Gray et al US Patent

5,714,472, Cope et al US Patent 5,700,782, Maubois et al US Patent 4427658, and Granger et al (JPEN 12:278-281,1988).

The instant claims are drawn to an enteral composition with caloric density of approximately 1.4 Kcal/ml and comprising a protein source, a carbohydrate source, a lipid source including a mixture of medium and long chain density triglycerides, a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, a L-Carnitine source, and a beta-carotene source. Further the instant claims encompass methods of providing said composition to a patient comprising administration of therapeutically effective amount to the patient.

The TRAUMACAL ™ Document bearing B00107-180 disclose that the use of a high protein-caloric density formula such as TRAUMACAL ™ provides a positive Nitrogen balance, and meets the nutritional needs of metabolically stressed patients specially when using a composition having a lower Non protein calories per nitrogen (pages 36 or B00143 last two paragraphs, 43 or B00149 last paragraph , 48 or B00154 last three paragraphs, 59 or B00165 last two paragraphs). The TRAUMACAL ™ Document bearing B00107-180, however, fails to incorporate a source of hydrolyzed whey protein in its formulation.

Trimbo et al teach the method of feeding patients with pulmonary disease by administering to a patient an enteral nutritional composition comprising a total calories not less than about 18% protein, about 20-50% carbohydrate, about 40-55% lipids comprising of a mixture of medium and long chain triglycerides, that meets US RDAs recommendations of all vitamins and minerals. Trimbo et al however fails to show the use of hydrolyzed whey protein and their production by

using pancreatic enzymes. Trimbo also fails to address the use of said enteral nutritional composition in metabolically stressed patients (see entire patent).

Stalker et al teach a method of providing a enteral nutritional formulation that meets the nutritional needs of malabsorbing patients comprising a caloric density of about 1.0 Kcal/ml comprising a protein source including protein hydrolysate comprising whey hydrolysate, a carbohydrate source, a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, and a Vitamin C source that meets U.S. RDAs recommendations of contained nutrients. Stalker et al teach a method for providing said formulation to a patient comprising the step of enterally administering to the patient a therapeutically effective amount (See entire patent). Stalker et al fail to address the usage of said formulation for metabolically stressed patients.

Schmidl et al teach an enteral nutritional formulation that meets the nutritional needs of critically ill and metabolically stressed patients such as patients suffering from trauma, burn, malnutrition, sepsis, cancer, AIDS or other like conditions (see Col 3, lines 34-42). Schmidl et al disclose an enteral formulation comprising a protein source that can provide approximately 16-25% of the calorie distribution of the composition that can include protein hydrolysate such as whey hydrolysate or alike (see Col 4 lines 51-67), a carbohydrate source, a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, a Vitamin C source (see Col 4 lines 1-51 and Col 8 table), and wherein said formulation provides a non-protein calorie to grams of nitrogen ratio of ranging from 150:1 to 80:1 (see Col 5 lines 64-68 and Col 6 lines 1-11). Schmidl et al also disclose a

method for providing said formulation to a patient comprising the step of enterally administering to the patient a therapeutically effective amount (see Col 7 lines60-67). However, Schmidl et al fail to incorporate beta-carotene and L-cystine to their enteral formula.

Cope et al US Patent 5,480,872 disclose a high protein, calorically dense (see col 5, lines 8-22) nutritional product for hypermetabolic patients comprising a hydrolyzed protein comprising any suitable source such as whey protein (see Col 9 line 20-46, and 1-12), a source of carbohydrate, a mixture of medium and long chain triglycerides and fatty acids, and other micronutrient such that the said nutritional product meets 100% US RDA's recommendations of all micronutrients contained (see tables 1, 2,5,6). Cope et al also disclose that the said nutritional product can be used both as an oral supplement and for enteral support, administered either orally or by tube feeding (see Col 13, lines 46-51). Cope's teachings along with the conversion factors that are known in the art (1gm carbohydrate=3.4Kcal, 1gm protein=4.0Kcal, 1gm Fat=9.0Kcal, and 1gm N=6.25g protein)enable one skilled in the art to formulate an enteral formula comprising a protein source comprising about 18-21% of the calorie distribution of the composition when admixing about 200g of carbohydrate source, about 24.5g of a lipid source, and about 60g of a protein source, while maintaining a caloric density of about 1.4 Kcal/ml, and Non-protein calorie per Nitrogen ratio of about 90:1.

Cope et al US Patent 5,700,782 disclose an enteral nutritional product with the caloric density of about 1.2 to 1.5 Kcal/ml comprising a protein source , a carbohydrate source (see col 9, lines 15-55) , a lipid source including a mixture of medium and long chain density triglycerides (see col 3 lines 49-66, and table 4), a Zinc source, a Vitamin C source, a Selenium source, a

Taurine source, a L-Carnitine source, a beta-carotene source, and other micronutrient that may be incorporated in the enteral product (see tables 2,3,4,5). Cope et al further disclose the method of providing said enteral or nutritional product to a patient (see col 5, lines 46-56, col 10, lines 13-53). According to the Cope's disclosure and the conversion factors known in the art (1gm carbohydrate=3.5Kcal, 1gm protein=4.0Kcal, 1gm Fat=9.0Kcal, and 1gm N=6.25g protein), an ordinary skilled artisan is able to formulate a liter of an enteral formula comprising a protein source comprising approximately 17-21% of the calorie distribution of the composition when admixing about 183g of carbohydrate source, about 38.5g of a lipid source, about 64g of a protein source, while maintaining a caloric density of about 1.3 Kcal/ml, and Non-protein calorie per Nitrogen ratio of about 92:1.

Gray et al teach an enteral nutritional formulation that meets the nutritional needs of critically ill and metabolically stressed patients such as post-surgical patients or patients suffering from trauma, burn or related complications. Said enteral formulation having a caloric density of at least 1.3 Kcal/ml comprising a protein source including protein hydrolysate comprising whey hydrolysate, a carbohydrate source, a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, and a Vitamin C source that meets U.S. RDAs recommendations of said nutrients (See col 5 lines 25-38, 65-68, and Col 6 lines 35-42, and Col 7, lines 0-14). Gray et al also disclose a method for providing said formulation to a patient comprising the step of enterally administering to the patient a therapeutically effective amount (Col 9 and 10).

Maubois et al disclose a method of obtaining hydrolyzed whey protein as well as an enteral nutritional formulation for use in an intesive care setting to the patients who may require a protein intake of the 7-25% of total caloric intake, wherein said protein comprising a hydrolyzed whey protein (see example 5 and 6). Maubois et al fail to specifically address the U.S. RDA's nutritional needs of metabolically stressed patients.

It is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Becket, 33 USPQ. 33 (C.C.P.A. 1937). In re Russell 439 F.2nd 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971). Further it is shown in the art that hypermetabolicly stressed patients may suffer from gastrointestinal malabsorption due to the changes of the intestinal mucosa and the intestinal capillary bed; subsequently, said patients experience enhanced protein absorption when a suitable hydrolyzed protein source (such as whey, because of its well balanced aminoacids content) is used (Granger et al, Page 280-281, see discussion). Therefore, it would have been obvious to one of ordinary skill in the art to use the teachings of Gray et al or Cope et al or Stalker and Maubois and further modify the TRAUMACAL ™ formulation (ex. using hydrolyzed whey protein) to provide an improved enteral product that meets the specific nutritional requirements of metabolically stressed patients. Similarly, it would have been obvious to one of ordinary skill in the art to utilize the teachings of Schmidl et al, Trimbo and Maubois to further modify TRAUMACAL ™ formulation to provide an improved enteral product that meets the specific nutritional requirements of metabolically stressed patients. In addition, it would have also been obvious to one of ordinary skill in the art to use the teachings of Schmidl et al and further modify the nutritional formulation of Cope et al US Patent 5480872 to provide an

improved enteral product that meets the specific nutritional requirements of metabolically stressed patients.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cope et al US Patent 5,547,927, 8/20/1996, also disclose an enteral nutritional product comprising a whey protein source, a lipid source, and a carbohydrate.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Sharareh whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Jose Dees can be reached on 703-308-4628. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

Shahnam Sharareh, PharmD

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SUPERVISORY PATENT EXAMINER
1616